510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Aug 29, 2005

1. Company and Correspondent making the submission:

Name – CyberMed, Inc.

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Contact – Mr. Song Nak Choi/ Manager

Internet – http://www.cybermed.co.kr

2. Device :

Trade/proprietary name	: Vimplant
Common Name	: Dental implant simulation software
Classification Name	: Picture archiving and communications system

3. Predicate Devices :

Manufacturer	: MATERIALISE N.V.
Device	: SimPlant System
510(k) Number	: K033849 (Decision Date – 05/25/2004)

Manufacturer:	CyberMed, Inc.
Device:	V-works™
510(k) Number:	K013878 (Decision Date – 12/07/2001)

4. Classifications Names & Citations :

21CFR 820.2050, LLZ, Picture archiving and communications system, Class2

5. Description :

1) General Description

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CyberMed, Inc.

VImplant™ is a dental implant simulation software for dentists and implantologists. By use of VImplant™, dental practicians can plan and practice their surgery in advance so they can reduce some risks which can happen during their real surgery.

VImplant™ provides very useful and needful functions. It contains functions of implant simulation, manipulation with 2D and 3D mode, nerve identification, and evaluation of bone density.

By using VImplant TM, dental practicians can quickly and easily simulate implant surgery on their desktop PCs. This enables them to conduct implant surgery more effectively by isolating the exact implant position site and angle and to assist in deciding the proper implant diameter, length, etc.

2) Main Function

   a. Import DICOM 3.0 data

     Users can import DICOM 3.0 data taken from CT to VImplant's database and manage them very easily on the patient list window of VImplant.

   b. 2D image reformation

     VImplant™ has the capability of reformatting panoramic images and cross-sectional images. So dental practicians can get the accurate anatomical knowledge of the patient on each view and know the exact relation of implant with nerve and bone before the implant surgery.

   c. 3D image construction

     VImplant™ has the capability of constructing 3D model from original axial images. The method of 3D image construction is Surface rendering and the reliability and validity were already verified in Vworks™. The 3D image can be edited by CT number(Hounsfield value) threshold.

   d. Nerve Creation and Display

     VImplant™ has nerve creation function to reduce some risks in placing an implant. Users can draw a nerve line on axial images, then arrange it on Panoramic view. And then users can see the intersection shape of nerve on each view. Also the nerve line is displayed in 3D model.

   e. Implant Simulation

VImplant™ provides users very useful functions for Implant simulation. Users can create and manipulate implants as they want. In the concrete, users can place an implant very easily by the mouse operation and also move and rotate it as they want. And also users can change some properties of the implant such as diameter, color and shape of the fixture and abutment part for their specific implant and then add it to Implant database. In addition, VImplant™ shows the implant in 3D model. So users can get the accurate position of implant in 3D model as well as 2D images.

f. Collision detection

VImplant™ has Collision detection function to prevent some collisions between nerve and implant or implant and implant as type of warning message.

g. Sinus bone graft

VImplant™ has Sinus bone graft function which estimate the volume of the material needed for bone grafting surgery.

h. Measurement and information

VImplant™ provides users needful measurement functions for implant planning such as bone density profile, length, angle. Specially users can measure the density distribution around a placed implant by use of Bone density function. And also users can see the distance between implant and implant or implant and nerve by use of 3D distance calculation function.

i. Report and Image Library

VImplant™ has the capabilliy of capturing all images and provides simple report form. Users can manage their images very easily in Image Library and also can send them to some storage such as PACS server.

3) Information of the image format

VImplant™ can load only DCM files and save results as DCM, BMP and JPG files.

- DCM : DICOM (Digital Image Communication in Medicine) is a Standard Protocol to exchange and transfer the data acquired by Medical Image devices such as a CT, MR, 3D US, etc. It is designated as a Standard Protocol by ACR-NEMA (American College of Radiology-National Electrical Manufacturers Association) and now adopted by most

Medical Imaging Devices. VImplantTM 2.0 is adaptable technically for all data of DICOM 3.0.

Reference : Digital Imaging and Communications in Medicine (DICOM) ACR-NEMA Standards Publication PS 3.1~PS 3.16 2003.

- BMP : The standard bit-mapped graphics format used in the Windows environment. By convention, graphics files in the BMP format end with a BMP extension. BMP files store graphics in a format called device-independent bitmap (DIB).

- JPG/JPEG : Short for "Joint Photographic Experts Group", the original name of the committee that wrote the standard. JPG is one of the image file formats supported on the Web. JPG is a lossy compression technique that is designed to compress color and grayscale continuous-tone images, but VImplant™ does not compress original graphics any more, that is to say lossless compression.

JPG images support 16 million colors and are best suited for photographs and complex graphics.

6. Indication for use :

The Vimplant is intended for use as a software interface for the transfer of imaging information from a CT scanner and also as a pre-operative software for simulation and evaluation dental implant placement and surgical treatment options.

7. Comparison with predicate device :

CyberMed, Inc., believes that the Vimplant Dental implant simulation software is substantially equivalent to SimPlant System of MATERIALISE N.V..

8. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification CyberMed, Inc. concludes that Vimplant is safe and effective and substantially equivalent to predicate devices as described herein.

9. CyberMed, Inc. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

NOV 2 3 2005

CyberMed, Inc.
% Mark M. Mouser
Senior Project Engineer/Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607-9526

Re.: K053155
Trade/Device Name: Vimplant™ Dental
                    implant simulation
                    software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
                    communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 19, 2005
Received: November 14, 2005

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
  Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): _K05 3155_

Device Name: Vimplant Dental implant simulation software

Indications for Use:

The Vimplant is intended for use as a software interface for the transfer of imaging information from a CT scanner and also as a pre-operative software for simulation and evaluation dental implant placement and surgical treatment options.

Prescription Use____✓____   AND/OR   Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D)   (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(signature)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number ____K0 53155____

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